

Remarks

The Office Action contains the following objections and rejections:

- 1) Claims 1, 15 and 26 were objected to as containing new matter;
- 2) Claims 1 and 2 were rejected under 35 U.S.C. §112, second paragraph; as being indefinite;
- 3) Claims 1-7, 9-11, 15-21 and 23, 24 and 26-28 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,489,346 ("Phillips I"); and
- 4) Claims 12-14, 25 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,840,737 ("Phillips II") in view of Phillips I.

The Office Action objected to claims 1, 15 and 26 as containing new matter on the grounds that there is no support for an equimolar ratio of a salt of a Group IA metal other than a carbonate or bicarbonate salt. The term "bicarbonate" was inadvertently omitted from claim 1 in the previous Amendment. This term has been reinserted. Accordingly, this objection should no longer apply.

This correction of claim 1 should also address the Section 112 rejection of claims 1 and 2 which should also be withdrawn.

Claims 30 – 33 have been added.

Phillips I discloses a composition comprising a non-enteric coated proton pump inhibitor and at least one buffering agent. While Phillips I does broadly state that mixtures of buffering agents can be used, there is not disclosure of any specific mixtures. Phillips I also states that sodium bicarbonate is the preferred buffering agent (column 13, lines 47-48). Furthermore; Phillips I also states that the buffering agent "must only elevate the ph of the stomach sufficiently to achieve adequate bioavailability of the drug" (column 13, lines 59-60).

The Office Action states that "there is a lack of support in the specification for the limitation 'an equimolar ratio' as now claimed." It is submitted that with the correction of claim 1, there is support for the limitation.

Phillips I does not disclose "an equimolar ratio" of a carbonate salt and a bicarbonate salt as is presently claimed. Thus Phillips I does not anticipate claims 1-7, 9-11, 15-21, 23, 24 and 26-28 and the Section 102(e) rejection should be withdrawn.

With respect to the Section 103(a) rejection, neither Phillips I nor Phillips II recognizes the problem addressed by the present invention. High doses of sodium bicarbonate produce large amounts of CO<sub>2</sub> and lead to belching which in patients with gastroesophageal reflux disease can worsen their condition. Furthermore, bicarbonates have lower acid – neutralizing capacity than carbonates permitting the use of lesser amounts of buffer and the formation of smaller pills or tablets (see pg. 5, line 23 – page 6, line 3 of the present application).

Since neither reference recognizes the problem addressed by the present invention and neither reference discloses or suggests the presently claimed composition, a prima facie case of obviousness does not exist and this rejection should be withdrawn.

In response to the conclusion in the Office Action that "the instant invention when taken as a whole, would have been prima facie obviousness," there is no suggestion of an equimolar ratio of bicarbonate and carbonate salts of Group IA metals as presently claimed.

Favorable consideration and allowance of claims 1-7, 9-21 and 23-33 as presently amended is respectfully requested.

If any fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 23-0785.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Martin L. Katz". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

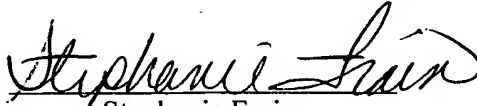
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I hereby certify that this Amendment is being deposited with the United States Postal Express Mail Service (EV 576550032 US) addressed to Box RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on February 9, 2006.

  
Stephanie Frain